

158. (New) The device of claim 106, further comprising a raised edge surrounding the target area opening in the body portion.

159. (New) The device of claim 109, further comprising a raised edge surrounding the target area opening in the body portion.--

### REMARKS

Applicants have cancelled claims 91 and 102, without prejudice or disclaimer, and have amended claims 81, 92-101, 103-112, 116, and 117. New claims 132-159 have been added and each of these claims is "readable on" at least the species elected in the Response to Restriction and Election of Species Requirement filed on June 29, 2001.

In the Office Action, claims 60, 61, 63-68, 70-72, and 74-70 [sic] were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 4,840,615 to Hancock et al.; claims 60-112 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 4,857,053 to Dalton; claims 81-85, 88, 89, 91-96, 99, and 100 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,108,377 to Cone et al.; claims 102-105, 107, 108, and 110-112 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent 5,718,682 to Tucker; claims 60-65, 68, 69, 81-85, 89-96, 100-107, 111, and 112 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 4,000,740 to Mittleman in view of Tucker; claims 62, 69, 73, 80, and 101 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hancock et al. or Cone et al. in view of Tucker; claims 113-131 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hancock et al., Dalton, Cone et al., Mittleman and/or Tucker in view of U.S. Patent 5,403,283 to Luther; and claims 113-131 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hancock et al.,

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Dalton, Cone et al., Mittleman and/or Tucker in view of U.S. Patent 5,556,381 to Ensminger et al. To the extent, if any, these rejections might be asserted to be applicable to the currently pending claims, Applicants respectfully disagree with these rejections.

As an initial matter, Applicants note it is not clear to what extent the Examiner has applied Hancock et al. to the claims because the rejection lists "claims 74-70." If the Examiner continues to reject the claims based on that reference, Applicants respectfully request that the Examiner clarify the rejection in the next written communication and also make any further Office Action non-final so that Applicants will have an adequate opportunity for response thereto.

#### **§ 102 Rejections**

Regarding the § 102(b) rejection of claims 60, 61, 63-68, 70-72, and 74-70 as being anticipated by Hancock et al. and the § 102(b) rejection of claims 60-80 as being anticipated by Dalton, Applicants respectfully disagree with these rejections. Each of independent claims 60 and 70 is directed to an access port device to be implanted in a patient's body wherein an outer surface of a septum forms a portion of an exterior surface of the device. Neither Hancock et al., nor Dalton discloses such subject matter.

The Examiner relies on Hancock et al. at col. 5, lines 16-20 for the asserted disclosure of an embodiment having a septum outer surface exposed exteriorly. See Office Action dated October 1, 2002, page 3. The specific passage relied on by the Examiner mentions that a sealing plate 28 is preferably made from biocompatible silicone rubber, but that "it does not need to be biocompatible unless it is exposed for contact with living tissue (not shown)." Hancock et al. does not include any other discussion of that arrangement and even acknowledges that such an arrangement is

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not shown. Furthermore, it is not clear how such a device would be configured because the drawings of Hancock et al. show an outer layer 26 covering the sealing plate 28. See Figs. 1-5. Therefore, Hancock et al. does not disclose an access port device including a septum "wherein an outer surface of the septum forms a portion of an exterior surface of the device." Hancock et al. cannot anticipate claims 60, 61, 63-68, 70-72, and 74-70 and the § 102(b) rejection based on that reference should be withdrawn.

Dalton discloses a silicone layer 66 that coats a matrix septum 20. See col. 6, lines 28-29. Dalton provides two examples requiring the entire port to be potted in a thin layer of silicone rubber. See col. 6, lines 51-66, and col. 7, lines 12-17. Another example requires a sandwich arrangement. See col. 7, lines 28-34. There is nothing in Dalton that teaches an access port device including a septum "wherein an outer surface of the septum forms a portion of an exterior surface of the device." Dalton cannot anticipate claims 60-80 and the § 102(b) rejection should be withdrawn.

Regarding the § 102(b) rejection of claims 81-101 as being anticipated by Dalton and the § 102(b) rejection of claims 81-85, 88, 89, 91-96, 99, and 100 as being anticipated by Cone et al., Applicants have amended independent claim 81, cancelled claim 91, and rewritten claims 97 and 98 in independent form. Neither Dalton, nor Cone et al. discloses the subject matter defined by these independent claims.

Dalton fails to disclose the subject matter of claims 81, 97, and 98 because the reference fails to disclose an access port device having an entry site "defined by a hole in the body portion," as required by the claims. As noted above, for example, Dalton discloses a silicone layer 66 that coats a matrix septum 20. There is nothing to suggest

that the silicone layer 66 or any other disclosed structure provides an entry site defined by a hole in a body portion. Therefore, Dalton cannot anticipate claims 81, 97, and 98 and the § 102(b) rejection of these claims should be withdrawn.

Turning now to Cone et al., that reference discloses a low profile injection port 20 having a port outlet connector 38 and a bore 40. The port outlet connector 38 and bore 40 act as a filter system. See, for example, col. 5, lines 21-29. Because of the arrangement of the port outlet connector 38 in the bore 40, the structure disclosed in Cone et al. is not configured "to permit insertion of one of a guidewire and a stylet through the body portion and into the outlet," as recited in claim 81. Therefore, the § 102(b) rejection of claim 81 based on Cone et al. should be withdrawn. Regarding claims 97 and 98, the Examiner did not reject these claims over Cone et al.

Turning to the § 102(b) rejection of claims 102-112 as being anticipated by Dalton and the § 102(e) rejection of claims 102-105, 107, 108, and 110-112 as being anticipated by Tucker, Applicants have cancelled claim 102 and rewritten claims 104, 106, and 109 in independent form. Neither Dalton, nor Tucker discloses the subject matter recited in independent claims 104, 106, and 109.

Dalton fails to disclose an access port device having an access site "defined by a target area opening in the body portion," as recited in claims 104, 106, and 109. As one of ordinary skill in the art would readily recognize, a target area is configured to facilitate making a determination of the orientation of an access site by skin palpation. Figs. 7-9 of the present application show one example of a target area 44 in the form of a region surrounded by a raised edge to facilitate determining orientation of the access site via

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skin palpation. Dalton fails to teach or suggest a target area opening in a body portion and, therefore, the § 102(b) rejection of claims 104, 106, 109 should be withdrawn.

Tucker fails to teach or suggest all of the subject matter recited in claims 104, 106, and 109. Regarding claim 104, Tucker fails to disclose an access port device where an entry site is "disposed opposite" an outlet. The reference discloses an access port device 10 and a top opening 20, but nothing in the reference suggests an entry site opposite an outlet. Therefore, Tucker fails to disclose the access port device recited in claim 104 and the § 102(e) rejection should be withdrawn. Regarding claims 106 and 109, the Examiner did not reject those claims over Tucker.

### **§ 103 Rejections**

Turning to the § 103(a) rejection of claims 60-65, 68, 69, 81-85, 89-96, 100-107, 111, and 112 over Mittleman in view of Tucker, Applicants respectfully disagree with this rejection. To establish a *prima facie* case of obviousness, three basic criteria must be satisfied. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify a reference or to combine references. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all the claim elements. See M.P.E.P. § 2143. Moreover, the requisite teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Applicant's disclosure. See *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). See M.P.E.P. § 706.02(j).

The claim rejection under 35 U.S.C. § 103(a) should be withdrawn due to a lack of the required criteria for a *prima facie* case of obviousness. As an initial matter, there

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would not have been any motivation or suggestion that would have led one of ordinary skill in the art to combine the references as proposed by the Examiner. Claims 60, 81, 104, 106, 109 all recite an access port device to be implanted in a patient's body wherein upper and lower body parts are formed of "implantable, biocompatible material."

Mittleman discloses an injection site 10 having a main body portion 12, first and second inlets 14, 16, and a diaphragm 26. As discussed in the Background of the Invention section of Mittleman, injection sites are commonly used in a hospital setting when it is desired to combine a medicament with a parental fluid (e.g., I.V. fluid) being fed to a patient intravenously. Col. 1, lines 7-11. Such devices are always positioned along tubing placed between the parental fluid source and the delivery device (e.g., needle) inserted in the patient without ever being implanted in the patient. Accordingly, there is no disclosure or suggestion of implantable, biocompatible material.

The Examiner asserts, at page 4 of the Office Action, that it would be obvious to modify Mittleman in view of Tucker "to provide a device compatible with bioactive fluids and to prevent injury during use that would result from the device moving in relation to the patient." This reasoning is clearly based on hindsight gained from Applicants' application. As mentioned above, the injection site of Mittleman would not be implanted within the body of a patient and, as such, there would be no plausible reason why one of ordinary skill in the art would look to Tucker for any asserted teaching of implantable, biocompatible material. Tucker provides no teaching or suggestion to modify the material of a non-implanted, parental injection site such as that taught by Mittleman.

Therefore, there is no motivation to combine the references as proposed by the

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Examiner, and the § 103(a) rejection of claims 61, 81, 104, 106, and 109 should be withdrawn.

Regarding the § 103(a) rejection of claims 62, 69, 73, 80, and 101 over Hancock et al. or Cone et al. in view of Tucker, Applicants respectfully disagree with this rejection because each of the claims depends from one of independent claims 60, 70, and 104, which are allowable over Hancock and Cone as discussed above. Therefore, this § 103(a) rejection of the claims should be withdrawn.

The rejection of claims 113-131 under § 103(a) as being unpatentable over Hancock et al., Dalton, Cone et al., Mittleman and/or Tucker in view of Luther and the rejection of claims 113-131 under § 103(a) as being unpatentable over Hancock et al., Dalton, Cone et al., Mittleman and/or Tucker in view of Ensminger et al. are improper. Regarding claims 113-117, each of those claims depends from one of independent claims 60, 70, 81, and 104, and is therefore allowable for at least the same reasons as the claims from which they depend. Therefore, the § 103(a) rejections of these claims should be withdrawn.

Regarding the § 103(a) rejection of claims 118-131, the Examiner has not indicated how Hancock et al., Dalton, Cone et al., Mittleman and/or Tucker have been applied to independent claims 118 and 125, so it is not clear how the references are being construed and further modified by Luther or Ensminger et al. If the Examiner insists on maintaining these rejections, Applicants respectfully request that the Examiner fully explain the proposed combinations in the next written communication and also make any further Office Action non-final so that Applicants will be afforded the opportunity to address the rejections.

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Claims 61-69, 71-81, 82-90, 92-96, 99-101, 103, 105, 107, 108, and 110-159 depend from one of independent claims 60, 70, 81, 97, 98, 104, 106, and 109 and are allowable for at least the same reasons as the independent claims from which they depend.

Applicants respectfully request that the Examiner reconsider this application, withdraw all of the claim rejections, and allow the pending claims in a timely manner.

The Office Action contains numerous assertions relating to the claims and the related art. Applicants decline to automatically subscribe to any assertion in the Office Action, regardless of whether any such assertion is discussed above.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated:

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**APPENDIX TO AMENDMENT**

**Version with Markings to Show Changes Made**

Amendments to the Claims

81. (Amended) An access port device to be implanted in a patient's body, the access port device comprising:

a body portion comprising an upper body part, a lower body part attachable to the upper body part, and a self-sealing septum between the upper body part and the lower body part,

wherein the upper body part and the lower body part are formed of implantable, biocompatible material, and

wherein a reservoir is defined by the body portion;

an outlet configured to be in flow communication with the reservoir; and

an entry site located on the body portion, the entry site being disposed opposite the outlet and being configured to permit insertion of one of a guidewire and a stylet through the body portion and into the outlet,

wherein the entry site is defined by a hole in the body portion, and wherein the device is configured to permit insertion of the one of the guidewire and the stylet through the body portion and into the outlet.

92. (Amended) The device of claim [91] 97, wherein the access site is located on the upper body part.

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93. (Amended) The device of claim [91] 97, wherein the entry site is disposed opposite the outlet.

94. (Amended) The device of claim [91] 97, wherein the implantable, biocompatible material is selected from acetal, titanium, and polysulfone.

95. (Amended) The device of claim [91] 97, wherein the entry site is located on the upper body part.

96. (Amended) The device of claim [91] 97, wherein the reservoir is defined between the septum and the lower body part.

97. (Amended) An access port device to be implanted in a patient's body,  
the access port device comprising:

a body portion comprising an upper body part, a lower body part  
attachable to the upper body part, and a self-sealing septum between the upper body  
part and the lower body part,

wherein the upper body part and the lower body part are formed of  
implantable, biocompatible material, and

wherein a reservoir is defined by the body portion;

an outlet configured to be in flow communication with the reservoir;

an entry site located on the body portion,

wherein the entry site is configured to permit access to the reservoir, and

wherein the entry site is defined by a hole in the body portion; and

an access site located on the body portion,

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wherein the access site is configured to permit access to the reservoir,

[The device of claim 91,] wherein the outlet extends away from the reservoir in a first direction, and

wherein the access site extends away from the reservoir in a second direction substantially perpendicular to the first direction.

98. (Amended) An access port device to be implanted in a patient's body,  
the access port device comprising:

a body portion comprising an upper body part, a lower body part  
attachable to the upper body part, and a self-sealing septum between the upper body  
part and the lower body part,

wherein the upper body part and the lower body part are formed of  
implantable, biocompatible material, and

wherein a reservoir is defined by the body portion;

an outlet configured to be in flow communication with the reservoir;

an entry site located on the body portion,

wherein the entry site is configured to permit access to the reservoir, and

wherein the entry site is defined by a hole in the body portion; and

an access site located on the body portion,

wherein the access site is configured to permit access to the reservoir,

[The device of claim 91,] wherein the entry site extends away from the reservoir in a first direction, and

wherein the access site extends away from the reservoir in a second direction substantially perpendicular to the first direction.

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99. (Amended) The device of claim [91] 97, wherein the septum comprises a unitary, single-piece construction comprising a first septum portion and a second septum portion, the first septum portion providing access to the reservoir via the entry site and the second septum portion providing access to the reservoir via the access site.

100. (Amended) An assembly comprising:

the device of claim [91] 97; and

a catheter connected to the outlet.

101. (Amended) The device of claim [91] 97, wherein the body portion comprises at least one suture hole configured to permit the device to be sutured inside the body of a patient.

103. (Amended) The device of claim [102] 104, wherein the access site is located on the upper body part.

104. (Amended) An access port device to be implanted in a patient's body,  
the access port device comprising:

a body portion comprising an upper body part, a lower body part  
attachable to the upper body part, and a self-sealing septum between the upper body  
part and the lower body part,

wherein the upper body part and the lower body part are formed of  
implantable, biocompatible material, and

wherein a reservoir is defined by the body portion;

an outlet configured to be in flow communication with the reservoir;

an entry site located on the body portion,

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wherein the entry site is configured to permit access to the reservoir, [The device of claim 102,] wherein the entry site is disposed opposite the outlet; and  
an access site located on the body portion,  
wherein the access site is configured to permit access to the reservoir,  
and  
wherein the access site is defined by a target area opening in the body portion.

105. (Amended) The device of claim [102] 104, wherein the implantable, biocompatible material is selected from acetal, titanium, and polysulfone.

106. (Amended) An access port device to be implanted in a patient's body,  
the access port device comprising:

a body portion comprising an upper body part, a lower body part  
attachable to the upper body part, and a self-sealing septum between the upper body  
part and the lower body part,

wherein the upper body part and the lower body part are formed of  
implantable, biocompatible material, and

wherein a reservoir is defined by the body portion;

an outlet configured to be in flow communication with the reservoir;

an entry site located on the body portion,

wherein the entry site is configured to permit access to the reservoir, [The device of claim 102,] wherein the entry site is located on the upper body part; and  
an access site located on the body portion,

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wherein the access site is configured to permit access to the reservoir,

and

wherein the access site is defined by a target area opening in the body

portion.

107. (Amended) The device of claim [102] 104, wherein the reservoir is defined between the septum and the lower body part.

108. (Amended) The device of claim [102] 104, wherein the outlet extends away from the reservoir in a first direction, and wherein the access site extends away from the reservoir in a second direction substantially perpendicular to the first direction.

109. (Amended) An access port device to be implanted in a patient's body,  
the access port device comprising:

a body portion comprising an upper body part, a lower body part  
attachable to the upper body part, and a self-sealing septum between the upper body  
part and the lower body part,

wherein the upper body part and the lower body part are formed of  
implantable, biocompatible material, and

wherein a reservoir is defined by the body portion;

an outlet configured to be in flow communication with the reservoir;

an entry site located on the body portion,

wherein the entry site is configured to permit access to the reservoir; and

an access site located on the body portion,

wherein the access site is configured to permit access to the reservoir,

and

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wherein the access site is defined by a target area opening in the body portion, [The device of claim 102,]

wherein the entry site extends away from the reservoir in a first direction,  
and

wherein the access site extends away from the reservoir in a second direction substantially perpendicular to the first direction.

110. (Amended) The device of claim [102] 104, wherein the septum comprises a unitary, single-piece construction comprising a first septum portion and a second septum portion, the first septum portion providing access to the reservoir via the entry site and the second septum portion providing access to the reservoir via the access site.

111. (Amended) An assembly comprising:  
the device of claim [102] 104; and  
a catheter connected to the outlet.

112. (Amended) The device of claim [102] 104, wherein the body portion comprises at least one suture hole configured to permit the device to be sutured inside the body of a patient.

116. (Amended) A system comprising:  
the access port device of claim [91] 97; and  
one of a guidewire and a stylet,  
wherein the entry site is configured to permit insertion of said one of a guidewire and a stylet through the body portion and into the outlet.

117. (Amended) A system comprising:

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the access port device of claim [102] 104; and

one of a guidewire and a stylet,

wherein the entry site is configured to permit insertion of said one of a guidewire and a stylet through the body portion and into the outlet.

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